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DEC 17 2003

510(k) Summary of Safety and Effectiveness
Palacos® G Bone Cement with Gentamicin

Submitter's Name and Address: Biomet Inc.,
P.O. Box 587
56 East Bell Drive
Warsaw, IN 46581

Contact Person: Lonnie Witham
Biomet Inc.
P.O. Box 587
Warsaw, IN 46581

Name of the Device: Palacos® G Bone Cement (with Gentamicin)

Legally marketed device to which the submitter claims substantial equivalence: Palacos® PMMA bone cement, FDA PMA No. P810020 (1984) – Subsequently reclassified into class II.

Description Of Palacos® G (with Gentamicin)
Palacos® G (with gentamicin) is a fast setting polymer (polymethylmethacrylate) cement for use in bone surgery. Mixing of the two sterile components, consisting of a powder and a liquid, initially produces a paste, which is used to anchor the prosthesis or to fill an osseous defect. The hardened bone cement allows stable fixation of the prosthesis and transfers stresses produced on movement to the bone via the large interface. Insoluble zirconium (IV) oxide is included in the cement powder as an x-ray contrast medium. The chlorophyll additive serves as optical marking of the bone cement at the site of the operation. The gentamicin component is a broad-spectrum antibiotic.

Material used:

40.8 grams powder	
Gentamicin sulfate (equivalent to 0.5 grams Gentamicin)	0.835 grams
Methyl acrylate-methyl methacrylate copolymer (6:94)	27.77 grams
Methyl acrylate-methyl methacrylate copolymer (42:58)	5.68 grams
Zirconium (IV) oxide (mono-clinic)	6.13 grams
Benzoyl peroxide	0.315 grams
Chlorophyll	0.008 grams (200 ppm)

Methylmethacrylate copolymer is the primary constituent of the powder component. Zirconium dioxide is added as a radio-pacifier. Chlorophyll is added as a colorant to distinguish polymer from bone at the site of operation. Benzoylperoxide is a starter. All are typical components of bone cement. Gentamicin® sulfate is an antibiotic that has been used in bone cement in Europe for approximately 20 years.

20 ml liquid

Methyl methacrylate	18.4 grams
N, N-Dimethyl-p-toluidine	0.38 grams
Chlorophyll	0.005 grams (200 ppm)

Methymethacrylate monomer is the primary constituent of the liquid component. In much smaller quantities are the accelerator, N, N-dimethyl-p-toluidine, and the stabilizer, hydroquinone, both of which are typical constituents of PMMA bone cement.

Scientific concepts, significant physical and performance characteristics:
When the powder and liquid components are mixed, the accelerator speeds the generation of free radicals and the stabilizer in the liquid reacts with many of the early free radicals, but is soon consumed. Free radicals can then initiate formation of polymer chains.

Polymerization proceeds slowly over the first few minutes. Polymer chains at the surface of the powder beads mingle with monomer and newly formed polymer chains, while smaller beads may dissolve completely. The cement temperature rises as set time of the cement approaches. Polymerization is essentially complete and the bone cement hard within 15 minutes.

Palacos® G with gentamicin is made of the same materials as the approved bone cements Palacos® R (P 810020). These materials have shown to be compatible and have a long history of clinical usage. Palacos® R with gentamicin has been used in Europe for approximately 20 years. Since Palacos® G (with gentamicin) is the same cement as Palacos® R approved in P810020 (1984) (no chemical constituents added nor removed), and gentamicin-impregnated Palacos® has a long history of clinical usage in Europe, no toxicological studies have been conducted.

Statement of intended use of the device:
Palacos® G with gentamicin is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared

Summary of the technological characteristics of the new device in comparison to those of the predicate device:
The components of Palacos® G (with gentamicin) are identical to the legally marketed device Palacos® R and are identically processed and sterilized. The only difference is the addition of gentamicin antibiotic to the powder component. Palacos® R impregnated with gentamicin has a long clinical history of use in Europe.

The effectiveness and substantial equivalence of Palacos® G (with gentamicin) was determined by in vitro mechanical comparative testing to Palacos® R and by comparing the relevant data. The results showed that Palacos® G (with gentamicin) possesses mechanical and chemical characteristics to fulfill its intended use.

In summary, Palacos® G with gentamicin is safe and effective for use in the above-mentioned indications. Palacos® G is substantially equivalent to Palacos® R for its primary intended use of fixation of prosthetic components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Mr. Lonnie Witham
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K030086
Trade/Device Name: Palacos® G Bone Cement with Gentamicin
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD and MBB
Dated: September 19, 2003
Received: September 22, 2003

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K030086

Device Name: Palacos® G Bone Cement with Gentamicin

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use NO (Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative & Neurological Devices

(510(k) Number) K030086